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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,220	11/27/2000	Wolfgang Fleischer	228.1006	8087

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,220

Applicant(s)

Fleischer

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 6, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 26, 29-47, and 51-53 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 26, 29-47, and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 and 8 6) ☐ Other:

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DETAILED ACTION

The amendment filed on 9-6-02 is acknowledged.

Claims included in the prosecution are 25-26, 29-47 and 51-53.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 25-26, 29-47 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposomes containing povidone iodine, does not reasonably provide enablement for generic ‘wound healing agent’ and anti-septic agent’ combined with a particulate carrier or various particles claimed in claim 2 and as set forth below. Instant specification does not provide adequate description of how one treat infections such as HIV just by applying numerous compounds falling under ‘anti-septic agents’ and ‘wound healing agents’ that too just by application to the throat. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.**

Instant claims are drawn to a method of administration of compositions in treating infections of nose, ears and throat. The claimed diseases include HIV. According to the

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specification even B vitamins come under the category of wound healing agents. There is no adequate disclosure of how a B vitamin can accomplish the claimed functions in the treatment of said disease, that too by application to nose, ears and throat. Instant specification does not provide adequate support for the broadly claimed 'antiseptic', anti-inflammatory agents and wound healing promoting agents and 'particulate carrier'; and opportunistic diseases. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to liposomally encapsulated povidone iodine and treatment of specific diseases.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that 'anti-septic agents' and 'wound healing agents' are known in the art. This might be so; however, applicant has provided neither data nor rationale for the ability of the agents such as B vitamins and Povidone Iodine in treating diseases such as HIV. In response, applicant argues that the presently claimed invention and methods cannot be used to prevent diseases such as HIV, but rather to treat and alleviate such treat such diseases, e.g., by treating opportunistic infections; the examiner points out that instant claim 46 which recites 'treatment of infectious diseases or alleviation of diseases such as HIV' shows it to be otherwise.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 26, 29, 33, 38, 39, 44, 45, 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The term, 'large' in claims 26 is a relative term and thus, indefinite. Applicant's arguments have been fully considered, but are not found to be persuasive. Instant specification does not provide a specific definition for this term.

The distinction between 'organic disinfectants' and rest of the components such as alcohols, phenols, etc., recited in claim 29 is unclear. The latter compounds are organic.

According to claim 25 the composition contains only one anti-septic agent and one wound healing agent; however, claim 33 recites, 'at least one'. This is improper.

What are 'conserving agents' and 'consistency-forming agents' as recited in claim 38?. Applicant's arguments that one skilled in the art would understand the terms are not persuasive since no evidence is provided.

What is being conveyed through claims 39? According to claim preamble, the carrier is a particulate carrier; then how can that be in a solution form? This claim requires a thorough restructuring. This rejection is maintained since applicant has not adequately addressed the issue.

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It is unclear whether PVP Iodine is encapsulated within the liposome or present outside as recited in claim 44.

Regarding claim 46 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It is unclear as to how 'angina' as recited in claim 47 is related to the ear, nose or throat.

The examiner once again suggests a thorough revision and restructuring of ALL the claims and submit a clear copy of the claims.

Double Patenting

- 6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).**

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. **Claims 25-26, 29-47 and 51-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24, 26-43, 51-57 of copending Application No. 09/701450. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reason. The claims in the copending application are drawn to treatment of lower respiratory tract by administration of the same composition. Since the administered composition has to travel through the throat to reach the lower respiratory tract, instant claims reciting 'throat' are deemed to be included in the method of administration in the claims of said copending application. There is an overlap between the portions of the respiratory tract and therefore, methods are obvious variants.**
- This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.**

Claim Rejections - 35 U.S.C. § 102

8. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 25-26, 35-39, 43, 46 and 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Knight (5,049,388).

Knight discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include antibiotics, antiviral agents and steroids (note the abstract, Tables I and II, examples and claims). The method of Knight enables the deposition of the liposomes throughout the respiratory tract which includes throat.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 25-26, 29-47 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 639 373 by itself or in combination with knight cited above.

EP discloses the same formulation. The compositions contain various claimed anti-septic agents and wound healing agents encapsulated in liposomes having diameters ranging from 20 nm to 20 microns. The method of application involves application of the composition to the mucous membranes and mucosa-like unkeratinized epithelial tissues of

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humans and animals. According to EP, the compositions can be in a variety of forms including, solutions, dispersions, creams, ointments and gels or any other such preparation (note abstract, pages 2-4, examples and claims). What is lacking in EP is the specific teaching that the mucosal surface to which the composition is applied is that present in the nose or throat. However, it would have been obvious to use the compositions and method of treatment of infections taught by EP to treat nose or throat, if the infections are present in these organs because said organs have mucous membranes; one of ordinary skill in the art would expect at least similar results. One of ordinary skill in the art would be motivated further, since Knight teaches that the infections of respiratory tract (which includes trachea) can be treated with liposomal compositions.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 26, 2002